

In the claims:

1. (Currently amended) A device for visualizing a structure located on the interior of a visually opaque substance relative to a region of interest in a body, the device comprising:

a marker member, the marker member composed of a biologically stable material, the marker member configured to permit ~~capable of permitting~~ non-obstructive visualization, via positron emission tomography and single photon emission computed tomography, of at least one structure located relative to the region of interest, the marker member having an interior defining a lumen, a proximal end, and a distal end, the lumen being closed at the distal end, and the distal end of the marker member being removably insertable in the visually opaque substance in proximate relationship to a cavity of potential space defined therein;

an external access member contiguously connected to the proximal end of the marker member, at least a portion of the external access member extending from the marker member to a location external to the visually opaque substance when the marker member is in removable insertable position in the visually opaque substance, the external access member including a gas metering device; [[and]]

an imaging material contained within the lumen via the closed distal end, ~~relative to the marker member in a manner~~ such that the imaging material does not directly contact the visually opaque substance, wherein the imaging material produces a signal detectable external to the visually opaque substance, the imaging material containing at least one radiopharmaceutical material, the imaging material producing an image detectable by positron emission tomography and single photon emission computed tomography, the gas metering device configured to movably position the imaging material at a discrete location relative to a longitudinal plane of the marker member; and

a pressure equalization member operatively connected to the lumen near or adjacent to the distal end.

2. (Original) The device of claim 1 wherein the imaging material is dispersed in an essentially homogenous manner through at least a portion of the interior of the marker member.

3. (Cancelled)

4. (Cancelled)

5. (Currently amended) The device of claim ~~[[4,]]~~1 wherein the gas metering device further comprising means for movably positioning the imaging material relative to the lumen ~~along the longitudinal plane of the lumen, the positioning means~~ is operable when the lumen is removably inserted in the visually opaque substance relative to the region of interest, and the ~~positioning means~~ gas metering device is located adjacent the proximal end of the lumen.

6. (Currently amended) The device of claim ~~[[4]]~~ 1 wherein the lumen is composed of a biologically stable material capable of permitting a non-obstructive visual image in and during the procedures that detect and translate the detectable signal resulting from the imaging material, such that the detection signal is sufficiently perceptible on the exterior of the substance to be imaged, the signal instrumentally detectable.

7. (Original) The device of claim 6 wherein the biologically stable material is one which prevents significant contact between the imaging material integrated or contained in the lumen and the surrounding visually opaque material.

8. (Currently amended) The device of claim ~~[[4]]~~ 1 wherein the lumen is at least partially flexible.

9. (Currently amended) The device of claim 8, further comprising:
an interior lumen positioned coaxially interior to the flexible lumen at a defined interior diametric distance therefrom, the interior lumen defining a central inner cavity, wherein the interior lumen and the ~~[[outer]]~~ flexible lumen define a coaxial space therebetween, and wherein the imaging material is contained external to the interior lumen.

10. (Previously presented) The device of claim 9, further comprising means for temporarily inflating the interior lumen and the associated outer flexible lumen into deformable

contact with the visually opaque substance, the inflating means located external to the visually opaque substance.

11. (Previously presented) The device of claim 1 wherein the visually opaque substance in which the device is adapted to be removably inserted includes an anatomical structure having a preexisting cavity of potential space, the cavity of potential space including at least one of oral cavity, nasopharynx, oropharynx, larynx, esophagus, uterus, urethra, vagina, urinary tract, gastrointestinal tract, and stomach.

12. (Cancelled)

13. (Cancelled)

14. (Cancelled)

15. (Original) The device of claim 1 wherein the imaging material is distributed in a flexible substrate material, the flexible substrate material being biologically non-reactive, stable and movably positionable relative to the interior of the marker member.

16. (Original) The device of claim 15 wherein the flexible substrate containing the imaging material is a fluid selected from the group consisting of water, propylene, glycol, and mixtures thereof.

17. (Original) The device of claim 15 wherein the flexible substrate containing the imaging material is a flexible, biologically compatible organic material selected from the group consisting of thermosetting polymers, thermoplastic polymers, waxes, organic sols, organic gels and mixtures thereof.

18. (Original) The device of claim 1 wherein the marker member has an interiorly oriented surface and an opposed exteriorly oriented surface, and wherein the imaging material is in contact with the interiorly oriented surface.

19. (Original) The device of claim 18 wherein the imaging material is bonded to the interiorly oriented surface of the marker member.

20. (Currently amended) A device for visualizing an anatomical structure located in ~~[[the]]~~ an interior of a visually opaque substance, the anatomical structure communicating with an external orifice, the device comprising:

a marker member, the marker member composed of a biologically stable material, the marker member having an interior defining a lumen, a proximal end, and a distal end, the lumen being closed at the distal end, and the distal end of the marker member ~~[[adapted]]~~ configured to be removably insertable in the anatomical structure defined in the visually opaque substance;

an external access member contiguously connected to the proximal end of the marker member, at least a portion of the external access member extending from the marker member to a location external to the visually opaque substance when the marker member is in removably insertable position in the anatomical structure in the visually opaque substance, the external access member including a gas metering device; [[and]]

an imaging material contained within the lumen via at least the closed distal end, ~~relative to the marker member in a manner~~ such that the imaging material does not directly contact the anatomical structure, the imaging material being a radiopharmaceutical compound having a radioisotope capable of producing a positron decay product, the imaging material producing a signal detectable external to the visually opaque substance wherein the decay product produced by the radiopharmaceutical compound produces products of an energy spectrum of varying wavelengths including at least one of photons, electrons, annihilation photons and positrons, ~~[[said]]~~ the products detectable by detection devices external to the visually opaque substance, the decay product detectable by positron emission tomography detectors and single photon emission computed tomography detectors, the gas metering device configured to movably

position the imaging material at a discrete location relative to a longitudinal plane of the marker member; and

a pressure equalization member operatively connected to the lumen near or adjacent to the distal end.

21. (Currently amended) The device of claim 20 wherein the ~~[[detectible]]~~ detectable decay product is generated by positron emission events and is detectable in a range between about 0.01 and about 2 cm.

22. (Original) The device of claim 20 wherein the anatomical structure visualized is at least one of oral cavity, nasopharynx, oropharynx, larynx, esophagus, rectum, uterus, urethra, vagina, urinary tract, and gastrointestinal tract.

23. (Original) The device of claim 22 wherein the radiopharmaceutical material produces a detectable gamma particle emission in a range between about 30 KeV and about 1000 KeV.

24. (Previously presented) The device of claim 20, further comprising a second imaging material comprising a CT contrast agent.

25. (Original) The device of claim 24 wherein the CT contrast agent is selected from the group consisting of iohexol, diatrizoate sodium, and mixtures thereof.

26. (Previously presented) The device of claim 20, further comprising a second imaging material comprising an MRI contrast agent.

27. (Original) The device of claim 26 wherein the MRI contrast agent is selected from the group consisting of gadopentate dimeglumine, gadolinium compounds, vitamin E containing compounds, and mixtures thereof.

28. (Currently amended) A device for visualizing anatomical structures located on the interior of a biological system, the device comprising:

a marker member, the marker member composed of a biologically stable material ~~capable of permitting~~ configured to permit non-obstructive visualization, via positron emission tomography and single photon emission computed tomography, of an anatomical structure of interest, the marker member having an interior defining at least one lumen, a proximal end, a distal end opposed to the proximal end, the at least one lumen being closed at the distal end, and the distal end removably insertable in a suitable cavity defined as an anatomical structure in the biological system;

an external access member contiguously connected to the proximal end of the marker member, at least a portion of the external access member extending from the marker member to a location external to the biological system when the marker member is in removable insertable position in the biological system, the external access member including a gas metering device; [[and]]

an imaging material contained within the at least one lumen via at least the closed distal end, ~~relative to the marker member~~ such that the imaging material does not directly contact the biological system, the imaging material producing a signal detectable external to the biological system and comprising at least one radiopharmaceutical material, the imaging material producing at least one decay product including at least one of photons, electrons, annihilation photons, and positrons, [[said]] the product detectable by detection devices external to the biological system, the detectable product detectable by positron emission tomography detectors and single photon emission computed tomography detectors; [[and]]

the gas metering device configured to ~~means for~~ movably position[[ing]] the imaging material at a discrete location relative to a longitudinal plane of the marker member while the marker member is in position in the biological system; and

a pressure equalization member operatively connected to the lumen near or adjacent to the distal end.

29. (Original) The device of claim 28 wherein the marker member is composed of a biologically stable material capable of permitting a non-obstructive visual image in and during

imaging procedures which detect and translate the detectable signal resulting from the imaging material, such that the detection signal is sufficiently readable on the exterior of the substance to be imaged, and the signal is instrumentally detectable.

30. (Previously presented) The device of claim 29, further comprising a second imaging material selected from the group consisting of:

- a. MRI contrast agents selected from the group consisting of paramagnetic compounds, and supermagnetic compounds;
- b. CT contrast agents selected from the group consisting of iohexol, diatrizoate sodium, and mixtures thereof;
- c. Ultrasound imaging materials; and
- d. mixtures thereof.

31. (Previously presented) The device of claim 30 wherein the second imaging material is dispersed in an essentially homogenous manner through at least a portion of the interior of the marker member.

32. (Original) The device of claim 29 wherein the biologically stable material of the marker member is one which prevents significant contact between the imaging material integrated or contained in the marker member and the surrounding biological system.

33. (Cancelled)

34. (Cancelled)

35. (Currently amended) The device of claim [[34]] 28 wherein the at least one lumen comprises:

an outwardly positioned, [[is]] at least partially flexible lumen, and wherein the marker member further comprises:; and

an interior lumen positioned coaxially interiorly to the ~~[[flexible]]~~ outwardly positioned lumen at a defined diametric distance therefrom, the interior lumen defining a central interior cavity, wherein at least one imaging material is positioned at a location in the marker member.

36. (Currently amended) The device of claim 35 wherein the imaging material is positioned at a location between the interior lumen and ~~[[the]]~~ an interior surface of the outwardly positioned lumen.

37. (Currently amended) The device of claim ~~[[35]]~~ 36, further comprising:
a second imaging material distinct from the imaging material contained between the outwardly positioned, at least partially flexible lumen and the interior lumen, the second imaging material contained in the central interior cavity in the interior lumen, wherein at least one of the imaging material and the second imaging material produces the signal detectable external to the biological system.

38. (Currently amended) The device of claim 37, further comprising means for temporarily inflating the interior lumen and the outwardly positioned ~~[[flexible]]~~ lumen into conforming contour with the cavity in the biological system.

39. (Currently amended) A method for visualizing structure in a body, the method comprising:

registering a first image with a second image, wherein the first image is derived from PET and SPECT, and the second image is derived from at least one of MRI, CT, or ultrasound, wherein the first and second images include at least one region of interest elucidated by a device removably inserted in the body, the removably inserted device including a marker member composed of a biologically stable material, wherein the marker member includes:

a. an interior defining a lumen, a proximal end, and a distal end, the lumen being closed at the distal end, and the distal end of the marker member being removably insertable in the body in proximate relationship to a cavity or potential space defined therein;

b. an external access member contiguously connected to the proximal end of the marker member, at least a portion of the external access member extending from the marker member to a location external to the body when the marker member is in a removably inserted position in the body, the external access member including a gas metering device; [[and]]

c. imaging material contained within the lumen via at least the closed distal end, ~~relative to the marker member in a manner~~ such that the imaging material does not directly contact the substance to be imaged, wherein the imaging material produces a signal detectable external to the body, the gas metering device configured to movably position the imaging material at a discrete location relative to a longitudinal plane of the marker member; and

d. a pressure equalization member operatively connected to the lumen near or adjacent to the distal end; and
removing the marker member having the imaging material therein after recording the images.

40. (Original) The method of claim 39 wherein the marker member is associated with at least one critical structure.

41. (Original) The method of claim 39 wherein the registration step comprises registration of at least two sequential images.

42. (Previously presented) The method of claim 39, further comprising verifying image registration.

43. (Original) The method of claim 42 wherein image registration verification includes at least one of point fiducial matching and landmark-based image registration.

44. (Original) The method of claim 42 wherein the image registration verification step comprises application of at least one mutual information-based automatic registration algorithm.

45. (Canceled)

46. (Original) The method of claim 39 wherein the registration step further comprises alignment of at least two intra-subject, intra-modality images.

47. (Original) The method of claim 39 wherein the registration step further comprises at least two intra-subject, inter-modality images.

48. (Original) The method of claim 39 wherein the registration step further comprises at least two inter-subject, inter-modality images.